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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,823	08/05/2003	Heinz-Josef Lenz	7000635001	1332

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,823	LENZ ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim is drawn to a kit, however, the claim does not recite any components present in the kit. The kit is defined in terms of what it is to be used for (i.e., "determining whether a subject has, or is at risk of developing colorectal cancer"), but the kit is not defined in terms of the reagents that are present in the kit. Accordingly, it is unclear as to what constitutes the claimed kit and thereby one cannot determine the meets and bounds of the claimed invention.

Claims 3 and 5 are indefinite over the recitation of "said first and second oligonucleotide" because this phrase lacks proper antecedent basis since the claims do not previously refer to oligonucleotides. Similarly, the phrases "the oligonucleotides" in claim 4 and "the first oligonucleotide" in claim 6 lack proper antecedent basis. It appears that each of these claims should depend from claim 2, rather than claim 1.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenchik et al (U.S. Patent No. 5,565,340).

Chenchik (column 11) teaches kits comprising DNA polymerase and a restriction endonuclease. DNA polymerase is a reagent that can be used to determine the molecular structure of the MnSOD gene. Further, all endonucleases are considered to be allele specific because they are capable of distinguishing between alleles having different nucleotide sequences. It is noted that the claims do not set forth a particular endonuclease nor do the claims set for a specific allele. Accordingly, Chenchik teaches kits comprising an allele specific endonuclease which can be used to determine the molecular structure of a portion of the MnSOD gene.

Additionally, it is noted that the recitation of "for determining whether a subject has, or is at risk of developing, colorectal cancer" merely sets forth the intended use or purpose of the claimed kits, but does not limit the scope of the claims. As stated in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999), if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable Ambrosone et al (Cancer Research (Feb 1999) 59: 602-606) in view of McCasky (U.S. Patent No. 6,100,030).

Ambrosone (page 602) teaches a mutation in the MnSOD gene at position –9 of the signal peptide which changes the amino acid at this position from valine (GTT) to alanine (GCT). Ambrosone (page 603) teaches detecting the –9 mutation (i.e., the mutation at nucleotide position 351) by amplifying MnSOD nucleic acid sequences using 2 primers specific for the MnSOD gene and amplification reagents and digesting the amplification products with the allele specific endonuclease Cac8 I. The Cac8 I restriction endonuclease cleaves amplification products containing the –9Ala allele, but not the –9Val allele. The primers disclosed by Ambrosone are 20 and 22 nucleotides in length. Ambrosone further teaches that the presence of the –9Ala allele is associated

with an increased risk of breast cancer in premenopausal women. Accordingly, the method of Ambrosone requires the use of primers for specifically amplifying the MnSOD gene and an allele specific endonuclease. Ambrosone does not teach packaging these reagents together in a kit.

However, McCasky (column 4) teaches the concept of kits comprising reagents useful for performing amplification reactions and detection methods.

In view of the teachings of McCasky, it would have been *prima facia* obvious to one of ordinary skill in the art at the time the invention was made to have packaged the reagents of Ambrosone of primers, amplification reagents and allele specific endonucleases into kits in view of the conventionality of kits in the diagnostic arts and in order to have obtained the advantages of convenience, cost-effectiveness, matched and/or preweighed components for practioners in the art wishing to detect the presence of the MnSOD –9 Ala/Val mutation.

Additionally, it is noted that the recitation of "for determining whether a subject has, or is at risk of developing, colorectal cancer" merely sets forth the intended use or purpose of the claimed kits, but does not limit the scope of the claims. As stated in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999), if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation."

With respect to claims 5-11, Ambrosone does not teach use of labeled, allele specific probes to distinguish between the Val and Ala alleles and thereby does not teach kits containing Ala and Val allele-specific probes.

However, McCasky teaches methods for detecting a mutation in a target nucleic acid using an allele specific probe (see, e.g., columns 21-22 and 24). The reference teaches that nucleic acids may be amplified by PCR and then detected using a labeled allele-specific probe in order to detect the presence of a mutation or polymorphism. McCasky (column 23) teaches that the probes are labeled with a fluorescent moiety and that one of the labels comprises a quencher, so that hybridization of the probe to the target nucleic acid is detected by quenching of the label.

In view of the teachings of McCasky, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ambrosone so as to have detected the MnSOD –9 Ala/Val mutation using labeled allele specific probes and particularly fluorescent / quencher labeled allele-specific probes, and to have packaged the labeled allele-specific probes in a kit. One would have been motivated to have done so in order to have provided an effective and rapid means for directly detecting the presence of the MnSOD –9 Ala/Val mutation.

With respect to claim 11, Ambrosone does not teach immobilizing the probe onto a solid support. However, McCasky (23-24) teaches immobilization of allele-specific probes onto solid supports, such as DNA chips, to allow for the simultaneous analysis of multiple samples and multiple mutations. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of

Ambrosone so as to have used immobilized allele-specific probes to a solid support such as a chip and to have packaged the immobilized allele-specific probes in kit in order to have provided an effective and rapid means for simultaneously analyzing multiple samples or multiple mutations in the MnSOD gene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Carla Myers
October 12, 2004

CARLA J. MYERS
PRIMARY EXAMINER